REMARKS

Claims 19-26 were rejected and remain pending. In light of the following remarks, Applicants respectfully request reconsideration and allowance of claims 19-26.

Rejections under 35 U.S.C. § 112, first paragraph

The Examiner maintained the rejection of claims 19-26 under 35 U.S.C. § 112, first paragraph, as allegedly not being enabled.

Applicants respectfully disagree. The presently claimed invention is fully enabled for all the reasons of record. The following remarks are in response to the Examiner's arguments presented in the Official Action mailed June 3, 2005, and provide additional evidence supporting the fact that Applicants' specification fully enables the presently claimed invention.

The Examiner's primary basis for rejecting the presently claimed invention appears to be the Examiner's belief that the field of gene therapy itself is not enabling as opposed to the use of the presently claimed invention in the field of gene therapy. In fact, the Examiner specifically stated that the "issues raised by the references cited by the examiner in the prior action relate to the unpredictability in the art of any method of gene therapy, such as cancer therapy . . ." (emphasis added). *See*, page 4, lines 1-2 of the Official Action mailed June 3, 2005. In addition, the Examiner stated that the Miller *et al.* reference (*Human Gene Therapy*, 8:803-815 (1997)) teaches that "the gene regulation system that ca[n] be applied to gene therapy in humans is yet unknown." The Examiner also stated that "Applicants do not demonstrate regulating any genes in humans or in any art recognized *in vivo* model."

From these and other statements, it appears that the Examiner believes that gene therapy will not be enabled until it is clinically available to humans. This is not the legal standard for patentability. As explained by the Federal Circuit, the patent office should not confuse "the requirements under the law for obtaining a patent with the requirements for obtaining government approval to market a particular drug for human consumption." *In re Brana*, 51 F.3d 1560, 1567, 34 USPQ2d 1436, 1442 (Fed. Cir. 1995). While the rejection on appeal in *In re*

Brana was an enablement rejection, the court discussed the issues in the context of both enablement and utility. In particular, the court stated that:

> Usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development. The stage at which an invention in this field becomes useful is well before it is ready to be administered to humans. Were we to require Phase II testing in order to prove utility, the associated costs would prevent many companies from obtaining patent protection on promising new inventions, thereby eliminating an incentive to pursue, through research and development, potential cures in many crucial areas such as the treatment of cancer.

Id. at 1568.

The principles of *In re Brana* apply equally to method claims relating to gene therapy. In fact, the U.S. Board of Patent Appeals and Interferences stated as much when reversing an enablement rejection similar to the present rejection. *See*, *Ex parte Jitka Forstova*, Appeal No. 1998-0667 Bd. Patent Appeals & Interferences, 2002 WL 32349992. Thus, under the proper standards as articulated by the Federal Circuit and the U.S. Board of Patent Appeals and Interferences, the present claims should be allowed. Applicants note that the Examiner, when addressing the specific subject matter of the presently claimed invention as opposed to making general statements about gene therapy, stated that the two steps recited in the present claims "may not require undue experimentation . . . ." *See*, page 4, lines 14-19 of the Official Action mailed June 3, 2005.

Even the art cited by the Examiner fails to support the Examiner's allegations that gene therapy is so unpredictable that a person having ordinary skill in the art can not practice gene therapy without undue experimentation. For example, the Crystal reference (*Science*, 270:404 (1995)) states that:

> [e]nough information has been gained from clinical trials to allow the conclusion that human gene transfer is feasible, can invoke biologic responses that are relevant to human disease, and can provide important insights into human biology.

See, first sentence of the Abstract. Although several sections of the cited references refer to apparent problems or obstacles in particular fact settings, the ability to overcome such problems or obstacles is not the standard for enablement. In particular, the U.S. Board of Patent Appeals and Interferences stated that:

> a number of the quotes relied upon by the examiner from the references refer to problems or obstacles in delivering the therapeutic to the target in a clinical setting. However, as stated in Brana, that is not the standard for enablement and/or utility.

See, Ex parte Jitka Forstova, Appeal No. 1998-0667 Bd. Patent Appeals & Interferences, 2002 WL 32349992

In light of the above, Applicant respectfully requests the withdrawal of the rejection of claims 19-26 under 35 U.S.C. § 112, first paragraph.

Rejections under 35 U.S.C. § 112, second paragraph

The Examiner rejected claims 19-26 under 35 U.S.C. § 112, second paragraph, as being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter applicant regards as the invention. Specifically, the Examiner stated that the definition of the term "altering" fails to limit the meaning of the term or otherwise provide guidance on the range of concentrations encompassed by the term.

Applicants respectfully disagree. The standard for indefiniteness is not whether a definition does or does not limit a term as the Examiner appears to contend. The second paragraph of 35 U.S.C. § 112 merely requires the specification to "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." To determine whether this requirement is satisfied, one must ascertain whether the claims set out the subject matter with a reasonable degree of clarity and particularity. The definiteness of claim language must be analyzed in light of: (1) the content of Applicant's specification; (2) the teachings of the prior art; and (3) the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. MPEP § 2173.02. In fact, the Federal Circuit has repeatedly stated that analysis

under 35 U.S.C. § 112, second paragraph "requires a determination of whether those skilled in the art would understand what is claimed when the claim is read in light of the specification." *See, e.g., Miles Laboratories, Inc. v. Shandon Inc.*, 997 F.2d 870, 875, 27 USPQ2d 1123, 1126 (Fed. Cir. 1993); and *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576, 1 USPQ2d 1081, 1088 (Fed Cir. 1986).

A person having ordinary skill in the art reading Applicants' specification and the present claims would have understood the meaning of the term "altering." In fact, the Examiner apparently had no problem understanding that the term "altering" encompasses "a range of changes from reducing the amount of drug administered to zero or raising it to near toxic levels." Thus, taken together, the present claims are clear and not ambiguous.

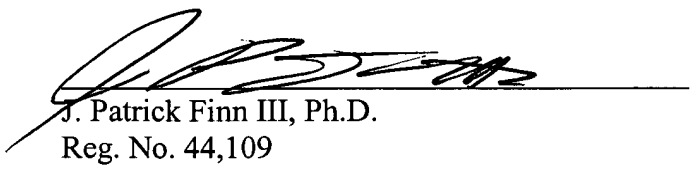
In light of the above, Applicants respectfully request the withdrawal of the rejection of claims 19-26 under 35 U.S.C. § 112, second paragraph.

CONCLUSION

Applicants submit that claims 19-26 are in condition for allowance, which action is requested. The Examiner is invited to call the undersigned attorney at the telephone number below if such will advance prosecution of this application. The Commissioner is authorized to charge any fees or credit any overpayments to Deposit Account No. 06-1050.

Respectfully submitted,

Date: August 3, 2005



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